

Notice of Allowability

Application No.

09/051,159

Examiner

Richard Schnizer, Ph. D

Applicant(s)

BALMAIN ET AL

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/15/2000.
2. ☐ The allowed claim(s) is/are 1-11,13,15,18-22 and 25.
3. ☒ The drawings filed on 4/2/98 and 9/3/04 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
- ☒ Examiner's Amendment/Comment
- ☐ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Note that the Quayle Action mailed 6/3/04 contained an Examiner's amendment to the claims.

The following Examiner's amendment was authorized in a telephone interview with Cynthia Kanik on 1/3/05, and consists of the addition of an abstract.

The application has been amended as follows:

After page 70, add the following abstract on a separate page:

Abstract

Compositions for targeting expression of a gene such as an antitumor gene may contain a first nucleic acid construct in which expression of a first gene is controlled by a first promoter whose function is suppressed in non-tumor cells, and a second nucleic acid construct in which expression of a second gene for down-regulating the first gene in non-tumor cells is controlled by a second promoter that is up-regulated in non-tumor cells. The second promoter may be regulated by means of p53 binding, targeting expression of the first gene to cells in which p53 down-regulation of expression is disrupted, e.g. cells in which p53 is mutated. The first promoter may be one which is upregulated in tumor cells, for example the Hsp70 promoter which is upregulated in mutant p53 tumor cells. A suitable antitumor agent is thymidine kinase.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

**DAVE TRONG NGUYEN
PRIMARY EXAMINER**

Richard Schnizer, Ph.D.



Art Unit: 1635

L1 1429 BALMAIN A?/AU OR BALMAIN A?/IN

=> s l1 and p53

50 FILES SEARCHED...

L2 243 L1 AND P53

=> s l2 and suppress?

32 FILES SEARCHED...

65 FILES SEARCHED...

L3 131 L2 AND SUPPRESS?

=> s l3 and (antitumor or anti tumor)

23 FILES SEARCHED...

39 FILES SEARCHED...

66 FILES SEARCHED...

L4 7 L3 AND (ANTITUMOR OR ANTI TUMOR)

=> dup rem l4

DUPLICATE IS NOT AVAILABLE IN 'ADISINSIGHT, ADISNEWS, BIOCOMMERCE, DGENE,

DRUGMONOG2, FEDRIP, FOREGE, GENBANK, IMSPRODUCT, IMSRESEARCH, KOSMET,

MEDICONF, NUTRACEUT, PCTGEN, PHAR, PHARMAML, PROUSDDR, RDISCLOSURE, SYNTHLINE'.

ANSWERS FROM THESE FILES WILL BE CONSIDERED UNIQUE

PROCESSING COMPLETED FOR L4

L5 3 DUP REM L4 (4 DUPLICATES REMOVED)

⇒ d bib ab 1-3

L6 6 (ZHU J?/AU OR ZHU J?/IN) AND P53 AND (ANTITUMOR OR ANTI TUMOR) AND PROMOTER

⇒

⇒ => d bib ab 1-6